

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

EPA MRID Number 47815102

**Data Requirement:** PMRA Data Code: 9.8.4 (TGAI) or 9.8.6 (EP)  
EPA DP Barcode: 317697  
OECD Data Point: IIA 8.12 (TGAI) and IIIA 10.8.1.1 (EP)  
EPA Guideline: 850.4250

**Test material:** Clarity 4.0 SL (AI: Dicamba)

**Purity:** 40.3% w/w

Common name

Chemical name: IUPAC 3,6-dichloro-o-anisic acid

CAS name 3,6-dichloro-2-methoxybenzoic acid

CAS No. 1918-00-9

Synonyms BAS 183 09 H

**Primary Reviewer:** Moncie Wright  
**Staff Scientist, Cambridge Environmental, Inc.**

**Signature:**

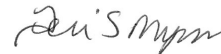
**Date:** 01/14/10



**Secondary Reviewer:** Teri S. Myers  
**Senior Scientist, Cambridge Environmental Inc.**

**Signature:**

**Date:** 01/15/10



**Primary Reviewer:** {.....}  
{EPA/OECD/PMRA}

**Date:** {.....}

**Secondary Reviewer(s):** {.....}  
{EPA/OECD/PMRA}

**Date:** {.....}

**Reference/Submission No.:** {.....}

**Company Code** {.....} [For PMRA]

**Active Code** {.....} [For PMRA]

**Use Site Category:** {.....} [For PMRA]

**EPA PC Code** 029801

**Date Evaluation Completed:** {dd-mm-yyyy}

**CITATION:** Porch, J.R., Krueger, H.O., Kendall, T.Z., and Holmes, C. 2009. BAS 183 09 H (Clarity): A toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants. Unpublished study performed by Wildlife International, Ltd., Easton, Maryland. Laboratory study no.: 147-236. Study sponsored by BASF Corporation, Research Triangle Park, North Carolina. Sponsor study no.: 358586. Study completed June 30, 2009.

**DISCLAIMER:** This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to terrestrial vascular plants. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

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## EXECUTIVE SUMMARY:

The effect of **Clarity 4.0 SL (AI: Dicamba)** on the vegetative vigor of monocot (corn, *Zea mays*; onion, *Allium cepa*; ryegrass, *Lolium perenne*; and wheat, *Triticum aestivum*) and dicot (cabbage, *Brassica oleracea*; carrot, *Daucus carota*; lettuce, *Lactuca sativa*; oilseed rape, *Brassica napus*; soybean, *Glycine max*; and tomato, *Lycopersicon esculentum*) crops was studied at nominal concentrations of 0 (negative and adjuvant control), 4.0, 8.0, 16, 32, and 64 fl. oz. form/A (corn, onion, ryegrass, and wheat); 0 (negative and adjuvant control), 0.0082, 0.025, 0.074, 0.22, 0.37, and 2.0 fl. oz. form/A (lettuce, soybean, and tomato); and 0 (negative and adjuvant control), 0.26, 0.79, 2.4, 7.1, 21, and 64 fl. oz. form/A (cabbage, carrot, and oilseed rape). Equivalent concentrations expressed in terms of the acid equivalent Dicamba were 0 (negative and adjuvant control), 0.13, 0.26, 0.51, 1.0, and 2.0 lbs ae/A (corn, onion, ryegrass, and wheat); 0 (negative and adjuvant control), 0.00026, 0.00080, 0.0024, 0.0070, 0.012, and 0.064 lbs ae/A (lettuce, soybean, and tomato); and 0 (negative and adjuvant control), 0.0083, 0.025, 0.077, 0.228, 0.67, and 2.0 lbs ae/A (cabbage, carrot, and oilseed rape).

Measured test concentrations were <0.0178 (<LOQ, controls), 0.125, 0.260, 0.515, 1.02, and 2.02 lbs ae/A (corn, onion, ryegrass, and wheat); <0.0178 (<LOQ, controls), 0.000261, 0.000751, 0.00227, 0.00676, 0.0196, and 0.0602 lbs ae/A (soybean and tomato); <0.0178 (<LOQ, controls), 0.00816, 0.0241, 0.0703, 0.215, 0.647, and 2.07 lbs ae/A (cabbage and carrot); <0.0183 (<LOQ, controls), 0.000262, 0.000766, 0.00225, 0.00697, 0.0210, and 0.0646 lbs ae/A (lettuce); and <0.0183 (<LOQ, controls), 0.00851, 0.0254, 0.0739, 0.222, 0.661, and 2.08 lbs ae/A (oilseed rape).

The growth medium used in the vegetative vigor test was artificial soil (sandy loam, pH 6.0, organic carbon 0.9%). On day 21 the surviving plants per pot were recorded and cut at soil level for measuring the plant height and dry weight.

Survival, dry weight and height were significantly affected in most dicot and some monocot crops.

The most sensitive monocot species was onion, based on dry weight, with NOAEC and EC<sub>25</sub> values of 0.515 and 0.472 lbs ae/A, respectively. The most sensitive dicot species was soybean, based on height, with NOAEC and EC<sub>25</sub> values of <0.000261 and 0.000513 lbs ae/A, respectively; for this most sensitive species, neither a NOAEC, EC<sub>05</sub>, nor EC<sub>10</sub> could be determined because they all fell below the lowest test level.

Phytotoxic effects included leaf curl, stem curl, chlorosis, and necrosis. There were no effects on ryegrass. Corn had scattered, mild effects that did not appear to be treatment-related. There were moderate effects on wheat. Soybean and onion experienced moderately severe effects. Cabbage, carrot, lettuce, oilseed rape, and tomato experienced severe effects. Species that were affected exhibited a dose-response relationship.

**Maximum Labeled Rate: Not reported**

## **Results Synopsis**

### *Acid equivalent*

#### Monocot

EC <sub>50</sub> /IC <sub>50</sub> : 1.12 lbs ae/A	95% C.I.: 0.690-1.80 lbs ae/A
EC <sub>25</sub> /IC <sub>25</sub> : 0.472 lbs ae/A	95% C.I.: 0.200-1.11 lbs ae/A
EC <sub>05</sub> /IC <sub>05</sub> : 0.137 lbs ae/A	95% C.I.: Not calculable
NOAEC: 0.515 lbs ae/A	
Slope: 1.80	95% C.I.: 1.13-4.50

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Most sensitive monocot: Onion  
Most sensitive parameter: Dry weight

## Dicot

EC<sub>50</sub>/IC<sub>50</sub>: 0.00670 lbs ae/A 95% C.I.: 0.00411-0.0109 lbs ae/A  
EC<sub>25</sub>/IC<sub>25</sub>: 0.000513 lbs ae/A 95% C.I.: Not calculable  
EC<sub>05</sub>/IC<sub>05</sub>: <0.000261 lbs ae/A 95% C.I.: N/A  
NOAEC: <0.000261 lbs ae/A  
Slope: 0.605 95% C.I.: 0.514-0.735  
Most sensitive dicot: Soybean  
Most sensitive parameter: Height

## *Formulation*

### Monocot

EC<sub>50</sub>/IC<sub>50</sub>: 2.78 lbs form/A 95% C.I.: 1.71-4.47 lbs form/A  
EC<sub>25</sub>/IC<sub>25</sub>: 1.17 lbs form/A 95% C.I.: 0.496-2.75 lbs form/A  
EC<sub>05</sub>/IC<sub>05</sub>: 0.340 lbs form/A 95% C.I.: Not calculable  
NOAEC: 1.28 lbs form/A  
Slope: 1.80 95% C.I.: 1.13-4.50  
Most sensitive monocot: Onion  
Most sensitive parameter: Dry weight

### Dicot

EC<sub>50</sub>/IC<sub>50</sub>: 0.0166 lbs form/A 95% C.I.: 0.0102-0.0270 lbs form/A  
EC<sub>25</sub>/IC<sub>25</sub>: 0.00127 lbs form/A 95% C.I.: Not calculable  
EC<sub>05</sub>/IC<sub>05</sub>: <0.000648 lbs form/A 95% C.I.: N/A  
NOAEC: <0.000648 lbs form/A  
Slope: 0.605 95% C.I.: 0.514-0.735  
Most sensitive dicot: Soybean  
Most sensitive parameter: Height

This toxicity study is classified as [enter acceptability classification, e.g., acceptable/unacceptable/supplementary] and satisfies/does not satisfy the guideline requirement for a Tier II vegetative vigor toxicity study.

**Table 1 (Tier II studies). Summary of most sensitive parameters by species (lbs ae/A).**

Species	Endpoint	NOAEC	EC <sub>05</sub>	EC <sub>25</sub>	EC <sub>50</sub>
Corn	None	2.02	>2.02	>2.02	>2.02
Onion	Dry weight	0.515	0.137	0.472	1.12
Ryegrass	None	2.02	>2.02	>2.02	>2.02
Wheat	Dry weight	0.26	<0.125	0.491	1.68
Cabbage	Dry weight	0.0241	0.227	0.695	1.51
Carrot	Dry weight	<0.00816	<0.00816	0.0657	0.493
Lettuce	Dry weight	0.00225	0.00548	0.0183	0.0424
Oilseed rape	Dry weight	0.0739	0.164	0.498	1.08
Soybean	Height	<0.000261	<0.000261	0.000513	0.00670
Tomato	Dry weight	<0.000261	<0.000261	0.000886	0.00333

## I. MATERIALS AND METHODS

**GUIDELINE FOLLOWED:** The methods used in conducting this study were based on procedures

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specified in the U.S. Environmental Protection Agency Series 850 – Ecological Effects Test Guidelines OPPTS Number 850.4150 and 850.4250. Deviations were noted:

1. The cation exchange capacity and moisture of the soil were not reported.
2. The NOAEC, EC<sub>05</sub>, and EC<sub>10</sub> could not be determined for soybean height (the most sensitive dicot species) because they all fell below the lowest test level. According to the US EPA memo entitled, “Closure on Nontarget Plant Phytotoxicity Policy Issues” on October 1994, if the lowest test level and the NOAEC are >EC<sub>10</sub>, but <EC<sub>25</sub>, the study may be classified as SUPPLEMENTAL. Additionally, determination of these lower toxicity values are recommended because they are useful for endangered species risk assessment.
3. The lowest readings of % relative humidity ranged from 10.9 to 20.5%; OPPTS guidelines suggest that relative humidity range from 70 ± 5% during light periods and 90% during dark periods. While the study authors did not report when the humidity readings were taken, the lower values greatly exceed light and dark recommendations. Corn, onion, ryegrass, and wheat relative humidity was a maximum of 78.6%; this value is above the recommended range for light periods, and is below the recommended range for dark periods. All other species had maximum relative humidity ranges of 90.5 to 92.6%; these values are acceptable for dark periods, but are above the recommended maxima for light periods.
4. Temperatures ranged from 14.7 to 32.7°C for corn, onion, ryegrass, wheat, cabbage, and carrot; OPPTS guidelines suggest day temperatures of 25 ± 3°C and night temperatures of 20 ± 3°C. The study authors did not differentiate between day and night temperatures; however, the lowest temperatures reported are lower than either the day or night recommendations, and the highest temperatures are higher than the recommended maxima for day and night.
5. Soybean, tomato, lettuce, and oilseed rape temperatures ranged from 17.2 to 35.7°C; the lowest value was within the acceptable lower end of the range of night temperatures, but was not within the acceptable range of day temperatures. The maximum temperature was well above the acceptable maxima for day and night temperatures.
6. Only five plants per replicate unit were tested; OPPTS guidelines suggest that 10 plants per replicate be tested.

These deviations did/did not impact the acceptability of the study.

### COMPLIANCE:

Signed and dated GLP, Quality Assurance and No Data Confidentiality statements were provided. The study was conducted in compliance with Good Laboratory Practice standards as published by the EPA in 40 CFR Part 160 (1989), OECD Principles of GLP (ENV/MC/CHEM(98)17), and Japan MAFF, 11 NohSan, Notification No. 6283 (1999), with the following exception:

Periodic analyses of soil and water for potential contaminants were not performed according to GLP standards, but were performed using a

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certified laboratory and standard EPA analytical methods.

## A. MATERIALS:

**1. Test Material** Clarity 4.0 SL (AI: Dicamba)

**Description:** Liquid

**Lot No./Batch No. :** 7054B01BJ

**Purity:** 40.3% ae w/w

**Stability of compound under test conditions:** Analytical verifications performed at the three different test initiation days (February 12, April 30, and May 14) yielded recoveries ranging from 91 to 102% of nominal test concentrations. *(OECD recommends chemical stability in water and light)*

**Storage conditions of test chemicals:** The test material, both components of the adjuvant, and the analytical standard were stored at ambient room conditions without exposure to sunlight.

**Table 2. Physical/chemical properties of Clarity 4.0 SL (AI: Dicamba).**

Parameter	Values	Comments
Water solubility at 20EC	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

## 2. Test organism:

**Monocotyledonous species:** Corn (*Zea mays*, Poaceae; Nothstine Dent), Onion (*Allium cepa*, Liliaceae; WI 3115), Ryegrass (*Lolium perenne*, Poaceae; Gator 3), and Wheat (*Triticum aestivum*, Poaceae; Alsen); *EPA recommends four monocots in two families, including corn.*

**Dicotyledonous species:** Cabbage (*Brassica oleracea*, Brassicaceae; Late Flat Dutch), Carrot (*Daucus carota*, Fabaceae; Scarlet Nantes), Lettuce (*Lactuca sativa*, Asteraceae; Summertime), Oilseed Rape (*Brassica napus*, Brassicaceae; Dwarf Essex), Soybean (*Glycine max*, Fabaceae; Williams 82), and Tomato (*Lycopersicon esculentum*, Solanaceae; Rutgers); *EPA recommends six dicots in four families, including soybean and a root crop.*

*OECD recommends a minimum of three species selected for testing, at least one from each of the following categories: Category 1: ryegrass, rice, oat, wheat, and sorghum; Category 2: mustard, rape, radish, turnip, and Chinese cabbage;*

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Category 3: vetch, mung bean, red clover, fenugreek, lettuce, and cress.

**Seed source:** Corn and wheat obtained from Johnny's Selected Seeds, Winslow, ME; onion obtained from Wannamaker Seeds, St. Matthews, SC; ryegrass, cabbage, carrot, and tomato obtained from The Meyer Seed Co., Baltimore, MD; lettuce obtained from Territorial Seed Co., Cottage Grove, OR; oilseed rape obtained from Seedland Inc., Wellborn, FL, and soybean obtained from Missouri Foundation Seeds, Columbia, MO.

**Prior seed treatment/sterilization:** Seeds were not treated with fungicides, insecticides, or repellents prior to test initiation.

**Historical % germination of seed:** Corn, 90%; onion, >85%; ryegrass, 90%; wheat, 96%; cabbage, 85%; carrot, 80%; lettuce, 98%; oilseed rape, 85%; soybean, 98%, and tomato, 80%.

**Seed storage, if any:** None reported.

## B. STUDY DESIGN:

### 1. Experimental Conditions

- a. Limit test: N/A This test was conducted as a Tier II test.
- b. Range-finding study A range-finding study was not reported.
- c. Definitive Study

Table 3: Experimental Parameters - Vegetative Vigor

Parameters	Vegetative Vigor	
	Details	Remarks
		Criteria
Duration of the test	21 days	<i>Recommended test duration is 14-21 days.</i>
Number of seeds/plants replicate	5 plants per replicate unit	<i>Five plants per replicate are recommended.</i>
Number of plants retained after thinning	Thinning not performed	
<u>Number of replicates</u>		
Control:	6	<i>Four replicates per dose are recommended</i>
Adjuvant control:	6	
Treated:	6	

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Parameters	Vegetative Vigor	
	Details	Remarks
		<i>Criteria</i>
<u>Test concentrations</u> Nominal (fl. oz. form/A):	<u>Corn, onion, ryegrass, and wheat:</u> 0 (negative and adjuvant control), 4.0,	

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Parameters	Vegetative Vigor	
	Details	Remarks
		Criteria
Nominal (lbs ae/A):	8.0, 16, 32, and 64 fl. oz. form/A <u>Lettuce, soybean, and tomato:</u> 0 (negative and adjuvant control), 0.0082, 0.025, 0.074, 0.22, 0.37, and 2.0 fl. oz. form/A <u>Cabbage, carrot, and oilseed rape:</u> 0 (negative and adjuvant control), 0.26, 0.79, 2.4, 7.1, 21, and 64 fl. oz. form/A	Five test concentrations should be used with a dose range of 2X or 3X progression
	<u>Corn, onion, ryegrass, and wheat:</u> 0 (negative and adjuvant control), 0.13, 0.26, 0.51, 1.0, and 2.0 lbs ae/A <u>Lettuce, soybean, and tomato:</u> 0 (negative and adjuvant control), 0.00026, 0.00080, 0.0024, 0.0070, 0.012, and 0.064 lbs ae/A <u>Cabbage, carrot, and oilseed rape:</u> 0 (negative and adjuvant control), 0.0083, 0.025, 0.077, 0.228, 0.67, and 2.0 lbs ae/A	
Measured:	<u>Corn, onion, ryegrass, and wheat:</u> <0.0178 (<LOQ, controls), 0.125, 0.260, 0.515, 1.02, and 2.02 lbs ae/A <u>Soybean and tomato:</u> <0.0178 (<LOQ, controls), 0.000261, 0.000751, 0.00227, 0.00676, 0.0196, and 0.0602 lbs ae/A <u>Cabbage and carrot:</u> <0.0178 (<LOQ, controls), 0.00816, 0.0241, 0.0703, 0.215, 0.647, and 2.07 lbs ae/A <u>Lettuce:</u> <0.0183 (<LOQ, controls), 0.000262, 0.000766, 0.00225, 0.00697, 0.0210, and 0.0646 lbs ae/A <u>Oilseed rape:</u> <0.0183 (<LOQ, controls), 0.00851, 0.0254, 0.0739, 0.222, 0.661, and 2.08 lbs ae/A	



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Parameters	Vegetative Vigor	
	Details	Remarks
		<i>Criteria</i>
<u>Method and interval of analytical verification</u>  LOQ: LOD:	Samples taken from each control and test level at test initiation and calibration standards were analyzed concurrently using HPLC with UV detection (235 nm).  100 mg ai/L Set at the lowest analytical standard analyzed	
Adjuvant (type, percentage, if used)	Non-ionic surfactant at 0.125% v:v and diammonium sulfate at 14 g/l	
<u>Test container (pot)</u>  Size/Volume Material: (glass/polystyrene)	11 cm diameter; 10 cm depth Plastic	Non-porous containers should be used.  OECD recommends that non-porous plastic or glazed pots be used.
Growth facility	Greenhouse	
Method/depth of seeding	The seeding method was not reported; corn, wheat, and soybean planted at depths of 20 mm; all other species planted at depths of 6 mm.	
<u>Test material application</u> Application time including the plant growth stage  Number of application  Application interval  Method of application	Test material was applied directly on seedlings with 2 to 5 open leaves.  1  N/A; single application  Applied using an overhead DeVries Research Tracksprayer equipped with a moveable spray nozzle suspended 41 cm above the target.	

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Parameters	Vegetative Vigor	
	Details	Remarks
		Criteria
<u>Details of soil used</u> Geographic location  Depth of soil collection Soil texture % sand % silt % clay pH: % organic carbon CEC Moisture at 1/3 atm (%)	N/A; artificial soil composed of kaolinite clay, industrial quartz sand and peat, with limestone added N/A Sandy loam 67 13 20 6.0 0.9% Not reported Not reported	Organic matter: 1.5%           <i>EPA prefers soil mixes containing sandy loam, loam, or clay loam soil with no greater than 2% organic matter. Glass beads, rock wool, and 100% acid washed sand are not preferred..</i>  <i>OECD prefers the soil to be sieved (0.5 cm) to remove coarse fragments. Carbon content should not exceed 1.5% (3% organic matter). Fine particles (under 20um) makeup should be between 10 and 20%. The recommended pH is between 5.0 and 7.5.</i>
Details of nutrient medium, if used	N/A	
<u>Watering regime and schedules</u> Water source/type:  Volume applied:  Interval of application:  Method of application:	Well water from the greenhouse.  Not reported.  Every 1 to 4 days.  The plants were bottom-watered using subirrigation trays.	        <i>EPA prefers that under foliage watering or bottom watering be utilized for vegetative vigor studies so that the chemical is not washed out of the soil during the test.</i>
Any pest control method/fertilization, if used		
<u>Test conditions</u> Temperature:	Corn, onion, ryegrass, and wheat:	

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Parameters	Vegetative Vigor	
	Details	Remarks
		Criteria
	14.7-31.6°C Soybean and tomato: 18.2-35.7°C Cabbage and carrot: 16.4-32.7°C Lettuce and oilseed rape: 17.2-32.3°C	<i>EPA prefers that the cold vs warm loving plants be tested in two separate groups to optimize plant growth.</i>  <i>OECD prefers that the temperature, humidity and light conditions be suitable for maintaining normal growth of each species for the test period.</i>
Photoperiod:	16L:8D	
Light intensity and quality:	High pressure sodium lighting used to supplement natural sunlight. Corn, onion, ryegrass, and wheat: 11.9-16.4 moles PAR Soybean and tomato: 11.0-16.4 moles PAR Cabbage and carrot: 10.4-14.7 moles PAR Lettuce and oilseed rape: 6.0-13.1 moles PAR	
Relative humidity:	Corn, onion, ryegrass, and wheat: 10.9-78.6% Soybean and tomato: 15.7-90.5% Cabbage and carrot: 20.5-91.8% Lettuce and oilseed rape: 20.1-92.6%	
Reference chemical (if used) Name: Concentrations:	N/A	
Other parameters, if any	None	

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## 2. Observations:

**Table 4: Observation Parameters - Vegetative Vigor**

Parameters	Vegetative Vigor	
	Details	Remarks
Parameters measured (i.e., plant height, dry weight or other endpoints)	<ul style="list-style-type: none"> <li>- Survival</li> <li>- Phytotoxicity</li> <li>- Dry weight</li> <li>- Height</li> </ul>	
Measurement technique for each parameter	Survival and phytotoxicity were determined visually. Height was measured with a ruler to the nearest whole centimeter from the soil surface to the apical meristem or to the tip of the tallest leaf. Dry weight was taken after the shoots of all living seedlings in a replicate were dried and weighed as a group (the weight of each replicate was divided by the number of seedlings).	
Observation intervals	Phytotoxicity and height were measured weekly. Survival and dry weight were determined at study termination.	
Other observations, if any	None	
Were raw data included?	Yes	
Phytotoxicity rating system, if used	0- No effect; 10-30- Slight effect; 40-60- Moderate effect; 70-90- Severe effect; 100- Complete effect	Frans, Robert E. and Ronald E. Talbert. 1977. Design of Field Experiments and the Measurement and Analysis of Plant Responses. Pages 15-23 in B. Truelove, ed. Research Methods in Weed Science. Southern Weed Science Society, Auburn University, Alabama.

## II. RESULTS and DISCUSSION:

### A. INHIBITORY EFFECTS:

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### Vegetative Vigor:

Survival was 100% in the negative and adjuvant controls. There were no inhibitions in survival for corn, ryegrass, and wheat. Soybean had a maximum inhibition in survival of 3%. Cabbage, onion, and lettuce had maximum inhibitions ranging from 27 to 40%. Carrot, oilseed rape, and tomato had maximum inhibitions ranging from 70 to 93%. Carrot inhibitions demonstrated a dose-response relationship.

There was actual promotion in height for ryegrass, with a maximum inhibition of -4%, and corn experienced only 1% inhibition in height. Carrot, wheat, lettuce, and cabbage had maximum inhibitions ranging from 15 to 24%. Onion and oilseed rape had inhibitions of 31 and 38%, respectively. Soybean and tomato had maximum inhibitions of 67 and 75%, respectively; both exhibited a dose-response relationship.

There was promotion of dry weight for corn, with a maximum inhibition of -5%, and ryegrass experienced only 1% inhibition in dry weight. Wheat, cabbage, carrot, lettuce, and onion had inhibitions ranging from 52 to 68%. Soybean, oilseed rape, and tomato had inhibitions ranging from 74 to 89%. All species except corn and ryegrass exhibited a dose-response relationship.

Based on the study authors' results, the most sensitive monocot species was onion, based on dry weight, with NOAEC and EC<sub>25</sub> values of 8.0 and 12.7 fl. oz form/A, respectively, which are equivalent to 0.26 and 0.41 lbs ae/A. The most sensitive dicot species was soybean, based on height, with NOAEC and EC<sub>25</sub> values of 0.0082 and 0.0194 fl. oz form/A, respectively, which are equivalent to 0.00026 and 0.00062 lbs ae/A.

Phytotoxic effects included leaf curl, stem curl, chlorosis, and necrosis. There were no effects on ryegrass. Corn had scattered, mild effects that did not appear to be treatment-related. There were moderate effects on wheat. Soybean and onion experienced moderately severe effects. Cabbage, carrot, lettuce, oilseed rape, and tomato experienced severe effects. Species that were affected exhibited a dose-response relationship.

### B. REPORTED STATISTICS:

Survival, dry weight, and height data were assessed. The study authors did not report comparing the negative and adjuvant control groups to evaluate potential effects of the adjuvant. The study authors pooled the control groups and used the pooled controls for all statistical analyses. The LOAEC and NOAEC values were determined using Dunnett's t-test via the DUNNETT option of the GLM (general linear model) procedure of SAS version 8 ( $\alpha = 0.05$ ). Estimates of the EC<sub>x</sub> values and their confidence limits were determined using the non-linear regression analysis of Bruce and Versteeg when reductions in endpoints among one or more treatment groups were 25% or more relative to the control means. These analyses were conducted using the NLIN procedure of SAS. The study authors reported toxicity values in terms of nominal concentrations of fl. oz form/A, and reported the most sensitive endpoints in terms of fl. oz form/A and lbs ae/A. The reviewer had to convert fl. oz form/A to lbs ae/A for all toxicity values for reporting in Tables 5 through 5c. Due to this conversion, toxicity values will be slightly different from those reported by the study author for the summary tables of the most sensitive endpoints.

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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**Table 5: Reported effect of Clarity 4.0 SL (AI: Dicamba) on Vegetative Vigor**

Species	Results summary for biomass (lbs ae/A)								
	Weight (g)	NOAEC	EC <sub>05</sub>	95%CI	EC <sub>25</sub>	95%CI	EC <sub>50</sub>	95%CI	LOAEC
Corn	1.00-1.23	2.1	ND	N/A	>2.1	N/A	>2.1	N/A	>2.1
Onion	0.04-0.15	0.26	ND	N/A	0.41	N/A	1.0	N/A	0.51
Ryegrass	0.70-0.92	2.1	ND	N/A	>2.1	N/A	>2.1	N/A	>2.1
Wheat	0.45-0.96	0.26	ND	N/A	0.53	N/A	1.8	N/A	0.51
Cabbage	1.70-4.62	0.025	ND	N/A	0.72	N/A	1.5	N/A	0.077
Carrot	0.50-1.28	0.025	ND	N/A	0.084	N/A	0.71	N/A	0.077
Lettuce	1.68-4.89	0.0024	ND	N/A	0.020	N/A	0.043	N/A	0.0071
Oilseed rape	1.08-4.23	0.077	ND	N/A	0.50	N/A	1.1	N/A	0.23
Soybean	1.86-7.21	0.00080	ND	N/A	0.0021	N/A	0.011	N/A	0.0024
Tomato	0.74-7.26	0.00026	ND	N/A	0.00092	N/A	0.0038	N/A	0.00080

**Table 5a: Reported effect of Clarity 4.0 SL (AI: Dicamba) on Vegetative Vigor**

Species	Results summary for height (lbs ae/A)								
	Height (cm)	NOAEC	EC <sub>05</sub>	95%CI	EC <sub>25</sub>	95%CI	EC <sub>50</sub>	95%CI	LOAEC
Corn	52-56	2.1	ND	N/A	>2.1	N/A	>2.1	N/A	>2.1
Onion	18-26	0.51	ND	N/A	1.1	N/A	>2.1	N/A	1.0
Ryegrass	22-23	2.1	ND	N/A	>2.1	N/A	>2.1	N/A	>2.1
Wheat	36-44	0.26	ND	N/A	>2.1	N/A	>2.1	N/A	0.51
Cabbage	17-23	0.67	ND	N/A	>2.1	N/A	>2.1	N/A	2.1
Carrot	27-35	0.23	ND	N/A	>2.1	N/A	>2.1	N/A	0.67
Lettuce	11-18	0.021	ND	N/A	0.063	N/A	>0.064	N/A	0.064
Oilseed rape	17-30	0.67	ND	N/A	1.3	N/A	>2.1	N/A	2.1
Soybean	18-54	0.00026	ND	N/A	0.00062	N/A	0.0079	N/A	0.00080
Tomato	11-44	0.0024	ND	N/A	0.0030	N/A	0.011	N/A	0.0071

\* provide the range

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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**Table 5b: Reported effect of Clarity 4.0 SL (AI: Dicamba) on Vegetative Vigor**

Species	Results summary for survival (lbs ae/A)								
	%	NOAEC	EC <sub>05</sub>	95%CI	EC <sub>25</sub>	95%CI	EC <sub>50</sub>	95%CI	LOAEC
Corn	100	2.1	ND	N/A	>2.1	N/A	>2.1	N/A	>2.1
Onion	63-100	0.51	ND	N/A	1.1	N/A	>2.1	N/A	1.0
Ryegrass	100	2.1	ND	N/A	>2.1	N/A	>2.1	N/A	>2.1
Wheat	100	2.1	ND	N/A	>2.1	N/A	>2.1	N/A	>2.1
Cabbage	73-100	0.67	ND	N/A	2.0	N/A	>2.1	N/A	2.1
Carrot	7-100	0.23	ND	N/A	0.44	N/A	0.71	N/A	0.67
Lettuce	60-100	0.021	ND	N/A	0.058	N/A	>0.064	N/A	0.064
Oilseed rape	30-100	0.23	ND	N/A	0.90	N/A	1.4	N/A	0.67
Soybean	97-100	0.064	ND	N/A	>0.064	N/A	>0.064	N/A	>0.064
Tomato	13-100	0.0071	ND	N/A	0.025	N/A	0.036	N/A	0.021

Plant Injury Index											
Control	Corn	Onion	Ryegrass	Wheat	Cabbage	Carrot	Lettuce	Oilseed rape	Soybean	Tomato	Adjuvant control
0-2	0-18	2-92	0	0-36	2-88	2-100	0-90	0-96	6-76	8-100	0-4

0- No effect; 10-30- Slight effect; 40-60- Moderate effect; 70-90- Severe effect; 100- Complete effect

## C. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

Statistical Method(s): All analyses were conducted using the negative control only. Analysis was conducted using Sprouts, a SAS program provided by EFED/OPP/USEPA, in SAS version 9. All endpoints for which replicate data were provided were examined graphically using graphs to determine if they exhibited a dose-dependent response, which was ultimately used to select the multiple comparison tests to detect the NOAEC. Data for each endpoint were tested to determine if their distributions were normal and if their variances were homogeneous using Shapiro-Wilk's and Levene's tests, respectively. Data that satisfied these assumptions were subjected to Dunnett's and William's tests and data that did not satisfy these assumptions were subjected to the non-parametric MannWhitney-U and Jonckheere's tests. Visual examinations of the Sprouts output in SAS were used to determine if there were significant differences between the negative and adjuvant controls.

All analyses were conducted using the measured reviewer-converted application rates of lbs acid equivalent per acre (lbs ae/A).

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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**Table 6: Effect of Clarity 4.0 SL (AI: Dicamba) on Vegetative Vigor**

Species	Results summary for biomass (lbs ae/A)									
	Weight (g)	NOAEC	EC <sub>05</sub>	95%CI	EC <sub>25</sub>	95%CI	EC <sub>50</sub>	95%CI	slope	95%CI
Corn	1.00-1.23	2.02	>2.02	N/A	>2.02	N/A	>2.02	N/A	N/A	N/A
Onion	0.04-0.15	0.515	0.137	NC	0.472	0.200-1.11	1.12	0.690-1.80	1.80	1.13-4.50
Ryegrass	0.70-0.92	2.02	>2.02	N/A	>2.02	N/A	>2.02	N/A	N/A	N/A
Wheat	0.45-0.96	0.26	<0.125	N/A	0.491	0.305-0.791	1.68	NC	1.26	0.968-1.81
Cabbage	1.70-4.62	0.0241	0.227	0.119-0.433	0.695	0.501-0.964	1.51	1.26-1.81	2.00	1.53-2.89
Carrot	0.50-1.28	<0.00816	<0.00816	N/A	0.0657	0.0243-0.178	0.493	0.278-0.876	0.771	0.570-1.189
Lettuce	1.68-4.89	0.00225	0.00548	0.00268-0.0112	0.0183	0.0127-0.0265	0.0424	0.0347-0.0520	1.85	1.42-2.67
Oilseed rape	1.08-4.23	0.0739	0.164	0.0833-0.323	0.498	0.341-0.728	1.08	0.866-1.34	2.01	1.56-2.84
Soybean	1.86-7.21	<0.000261	<0.000261	N/A	0.00160	0.000702-0.00364	0.00960	0.00589-0.0157	0.866	0.700-1.13
Tomato	0.74-7.26	<0.000261	<0.000261	N/A	0.000886	0.000442-0.00178	0.00333	0.00212-0.00524	1.17	0.957-1.51

NC=Not calculable



# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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**Table 6a: Effect of Clarity 4.0 SL (AI: Dicamba) on Vegetative Vigor**

Species	Results summary for height (lbs ae/A)									
	Height (cm)	NOAEC	EC <sub>05</sub>	95%CI	EC <sub>25</sub>	95%CI	EC <sub>50</sub>	95%CI	slope	95%CI
Corn	52-56	2.02	>2.02	N/A	>2.02	N/A	>2.02	N/A	N/A	N/A
Onion	18-26	0.515	<0.125	N/A	1.04	NC	>2.02	N/A	0.905	0.482-7.49
Ryegrass	22-23	2.02	>2.02	N/A	>2.02	N/A	>2.02	N/A	N/A	N/A
Wheat	36-44	0.26	0.534	0.269-1.063	>2.02	N/A	>2.02	N/A	1.21	0.821-2.28
Cabbage	17-23	0.647	>0.647	N/A	>2.07	N/A	>2.07	N/A	N/A	N/A
Carrot	27-35	0.215	>0.215	N/A	>2.07	N/A	>2.07	N/A	N/A	N/A
Lettuce	11-18	0.021	>0.021	N/A	>0.0646	N/A	>0.0646	N/A	N/A	N/A
Oilseed rape	17-30	0.661	0.529	0.286-0.976	1.33	1.06-1.68	>2.08	N/A	2.41	1.67-4.38
Soybean	18-54	<0.000261	<0.000261	N/A	0.000513	NC	0.00670	0.00411-0.0109	0.605	0.514-0.735
Tomato	11-44	0.000751	0.000577	NC	0.00290	0.00179-0.00470	0.00891	0.00666-0.0119	1.38	1.13-1.78

NC=Not calculable

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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**Table 6b: Effect of Clarity 4.0 SL (AI: Dicamba) on Vegetative Vigor**

Species	Results summary for survival (lbs ae/A)									
	%	NOAEC	EC <sub>05</sub>	95%CI	EC <sub>25</sub>	95%CI	EC <sub>50</sub>	95%CI	slope	95%CI
Corn	100	2.02	>2.02	N/A	>2.02	N/A	>2.02	N/A	N/A	N/A
Onion	63-100	0.26	0.404	0.165-0.602	1.19	0.858-1.78	2.52	NC	117	13.2-1031
Ryegrass	100	2.02	>2.02	N/A	>2.02	N/A	>2.02	N/A	N/A	N/A
Wheat	100	2.02	>2.02	N/A	>2.02	N/A	>2.02	N/A	N/A	N/A
Cabbage	73-100	0.647	1.72	N/A	2.05	N/A	>2.07	N/A	NC	N/A
Carrot	7-100	0.0703	0.133	0.0688-0.200	0.332	0.227-0.442	0.625	0.471-0.852	282	55.0-1451
Lettuce	60-100	0.021	0.0513	N/A	0.0603	N/A	>0.0646	N/A	NC	N/A
Oilseed rape	30-100	0.222	0.474	0.235-0.670	0.915	0.638-1.17	1.44	1.13-1.95	2515	116-54460
Soybean	97-100	0.0602	>0.0602	N/A	>0.0602	N/A	>0.0602	N/A	N/A	N/A
Tomato	13-100	0.00676	0.0138	0.00821-0.0184	0.0232	0.0171-0.0286	0.0331	0.0267-0.0414	21275	663-682893

NC=Not calculable

Plant Injury Index											
Control	Corn	Onion	Ryegrass	Wheat	Cabbage	Carrot	Lettuce	Oilseed rape	Soybean	Tomato	Adjuvant control
0-2	0-18	2.92	0	0-36	2-88	2-100	0-90	0-96	6-76	8-100	0-4

0- No effect; 10-30- Slight effect; 40-60- Moderate effect; 70-90- Severe effect; 100- Complete effect

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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## Monocot

EC<sub>50</sub>/IC<sub>50</sub>: 1.12 lbs ae/A 95% C.I.: 0.690-1.80 lbs ae/A

EC<sub>25</sub>/IC<sub>25</sub>: 0.472 lbs ae/A 95% C.I.: 0.200-1.11 lbs ae/A

EC<sub>05</sub>/IC<sub>05</sub>: 0.137 lbs ae/A 95% C.I.: Not calculable

NOAEC: 0.515 lbs ae/A

Slope: 1.80 95% C.I.: 1.13-4.50

Most sensitive monocot: Onion

Most sensitive parameter: Dry weight

## Dicot

EC<sub>50</sub>/IC<sub>50</sub>: 0.00670 lbs ae/A 95% C.I.: 0.00411-0.0109 lbs ae/A

EC<sub>25</sub>/IC<sub>25</sub>: 0.000513 lbs ae/A 95% C.I.: Not calculable

EC<sub>05</sub>/IC<sub>05</sub>: <0.000261 lbs ae/A 95% C.I.: N/A

NOAEC: <0.000261 lbs ae/A

Slope: 0.605 95% C.I.: 0.514-0.735

Most sensitive dicot: Soybean

Most sensitive parameter: Height

## **D. STUDY DEFICIENCIES:**

The NOAEC, EC<sub>05</sub>, and EC<sub>10</sub> could not be determined for soybean height (the most sensitive dicot species) because they all fell below the lowest test level. According to the US EPA memo entitled, "Closure on Nontarget Plant Phytotoxicity Policy Issues" on October 1994, if the lowest test level and the NOAEC are >EC<sub>10</sub>, but <EC<sub>25</sub>, the study may be classified as SUPPLEMENTAL. Additionally, determination of these lower toxicity values are recommended because they are useful for endangered species risk assessment.

## **E. REVIEWER'S COMMENTS:**

The study authors' and the reviewers' results were in agreement with regard to both the most sensitive monocot and dicot species. However, the toxicity values obtained were different. The study authors' NOAEC and EC<sub>25</sub> values for onion, based on dry weight, were 0.26 and 0.41 lbs ae/A, respectively. The reviewer's NOAEC and EC<sub>25</sub> values were 0.515 and 0.472, which were both higher (less conservative) than the study authors' reported values. The study authors' NOAEC and EC<sub>25</sub> values for soybean, based on height, were 0.00026 and 0.00062 lbs ae/A, respectively. The reviewer's NOAEC and EC<sub>25</sub> values were <0.000261 and 0.000513, which were both lower (more conservative) than the study authors' reported values. However, the reviewer used measured application rates and obtained 95% confidence intervals, whereas the study authors used nominal rates and did not report the confidence intervals. Therefore, the reviewer's results are presented in the Executive Summary and Conclusions sections of this DER.

The reviewer recommends testing soybean at lower test levels to define a NOAEC, EC<sub>05</sub>, and EC<sub>10</sub> for this species; these values could not be determined for soybean height (the most sensitive dicot species) because they all fell below the lowest test level. According to the US EPA memo entitled, "Closure on Nontarget Plant Phytotoxicity Policy Issues" on October 1994, if the lowest test level and the NOAEC are >EC<sub>10</sub>, but <EC<sub>25</sub>, the study may be classified as SUPPLEMENTAL. Additionally, determination of these lower toxicity values are recommended because they are useful for endangered species risk assessment.

Corn, onion, ryegrass, and wheat were tested at measured application rates of 0.0178 (<LOQ, controls), 0.125, 0.260, 0.515, 1.02, and 2.02 lbs ae/A. Soybean and tomato were tested at measured rates of 0.0178 (<LOQ, controls), 0.000261, 0.000751, 0.00227, 0.00676, 0.0196, and 0.0602 lbs ae/A. Cabbage and carrot were tested at measured rates of 0.0178 (<LOQ, controls), 0.00816, 0.0241, 0.0703, 0.215, 0.647, and 2.07 lbs ae/A.

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Lettuce was tested at measured rates of 0.0183 (<LOQ, controls), 0.000262, 0.000766, 0.00225, 0.00697, 0.0210, and 0.0646 lbs ae/A. Oilseed rape was tested at measured rates of 0.0183 (<LOQ, controls), 0.00851, 0.0254, 0.0739, 0.222, 0.661, and 2.08 lbs ae/A.

The study author only reported toxicity values in lbs ae/A for the most sensitive endpoints for each species; therefore, the reviewer had to convert the nominal concentrations reported by the study author in fl. oz form/A to lbs ae/A in order to report the study authors' findings in the Reported Effects tables.

The reviewer visually compared the negative and adjuvant control data for each species and endpoint to determine if there were significant differences. Ryegrass weight was the only case where the negative and adjuvant controls were notably different, and there was a 17% promotion in weight in the adjuvant control as compared to the negative control. This effect was isolated to this one species and endpoint combination, leading the reviewer to conclude that there were no impact of the adjuvant on the effects of the test material in this study.

Replicate C in the lettuce 0.67 fl. oz form/A treatment group, and replicate B in the soybean 0.025 fl. oz form/A treatment group were dropped from the study authors' analysis due to a lack of water until day 7 after test initiation. The reviewer also dropped these replicates from analysis.

The in-life portion of the test with corn, onion, ryegrass, and wheat was conducted from February 12 to March 5, 2009. The test with cabbage, carrot, soybean, and tomato was conducted from April 30 to May 21, 2009. The test with lettuce and oilseed rape was conducted from May 14 to June 4, 2009.

An initial test with tomato, lettuce, soybean, and cabbage was conducted from March 18 to April 8, 2009, and with carrot and oilseed rape from February 12 to March 5; however, the tests were repeated with different rates to obtain a clear dose-response relationship.

## F. CONCLUSIONS:

**Indicate if the study is acceptable/unacceptable/supplementary.** The most sensitive monocot species was onion, based on dry weight, with NOAEC and EC<sub>25</sub> values of 0.515 and 0.472 lbs ae/A, respectively. The most sensitive dicot species was soybean, based on height, with NOAEC and EC<sub>25</sub> values of <0.000261 and 0.000513 lbs ae/A, respectively.

Most sensitive monocot and EC<sub>25</sub>: Onion (dry weight; 0.472 lbs ae/A)

Most sensitive dicot and EC<sub>25</sub>: Soybean (height; 0.000513 lbs ae/A)

## III. REFERENCES:

1. U.S. Environmental Protection Agency. 1996. Series 850 – Ecological Effects Test Guidelines (*draft*), OPPTS Number 850.4150: Terrestrial Plant Toxicity, Tier I (Vegetative Vigor).
2. U.S. Environmental Protection Agency. 1996. Series 850 – Ecological Effects Test Guidelines (*draft*), OPPTS Number 850.4250: Vegetative Vigor, Tier II.
3. Frans, Robert E. and Ronald E. Talbert. 1977. Design of Field Experiments and the Measurement and Analysis of Plant Responses. Pages 15-23 in B. Truelove, ed. *Research Methods in Weed Science*. Southern Weed Science Society, Auburn University, Alabama.
4. Bruce, Robert D. and Donald J. Versteeg. 1992. A Statistical Procedure for Modeling Continuous Toxicity Data. *Environmental Toxicology and Chemistry*. 11: 1485-1494.

# **Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor**

**PMRA Submission Number {.....}**

**EPA MRID Number 47815102**

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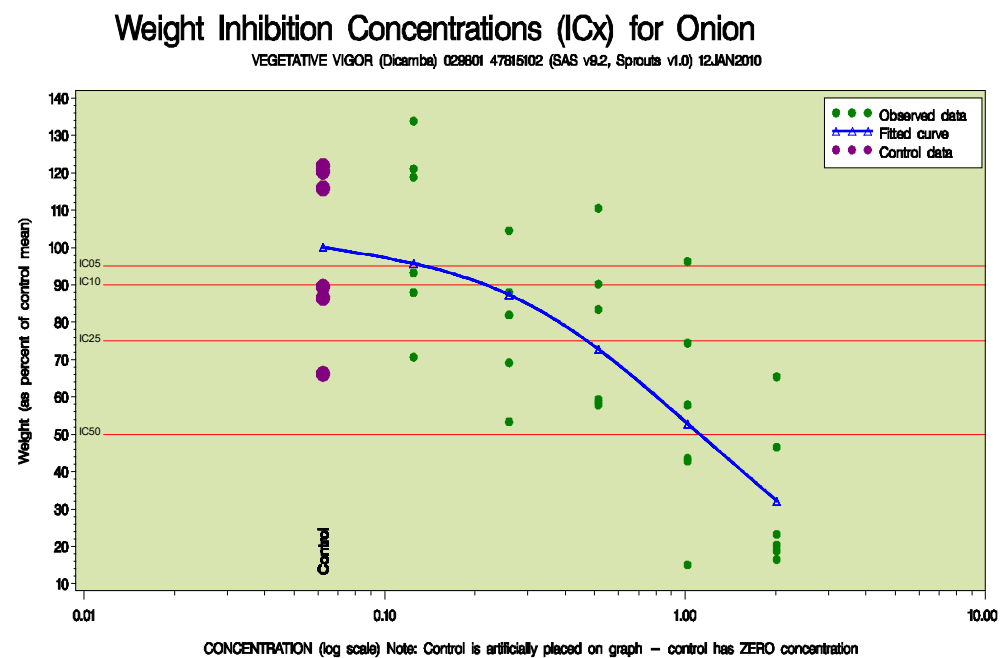
5. SAS Institute, Inc. 1999. SAS Proprietary Software Version 8, Cary, NC, SAS Institute, Inc.

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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## APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:



# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

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Analysis results for Variable: **WEIGHT Onion**

(SAS v9.2, Sprouts v1.0) VEGETATIVE VIGOR (Dicamba) 029801 47815102 12JAN2010

\*\*\*\*\*

Comparing Control vs. Inactive Ingredient

Class	N	Mean	LowerCL	UpperCL	StdDev	StdErr	Minimum	Maximum
Control	6	0.1330	0.1013	0.1647	0.0302	0.0123	0.0880	0.1620
Inactive	6	0.1473	0.1128	0.1819	0.0329	0.0134	0.1030	0.1830
Diff (1-2)	—	-0.0143	-0.0550	0.0263	0.0316	0.0182	—	—

\*\*\*\*\*

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals --- alpha-level=.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=.05

Use parametric analysis if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks	Shapiro-Wilks	Levenes	Levenes	Conclusion
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Test Stat	P-value	Test Stat	P-value	
0.964	0.283	0.554	0.734	USE PARAMETRIC TESTS

\*\*\*\*\*

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	CV(%)	95% Confidence Interval
-1.000000	6	0.133000	0.030186	0.012323	22.70	0.101322, 0.164678
0.125000	6	0.138667	0.031935	0.013038	23.03	0.105153, 0.172181
0.260000	6	0.106167	0.023017	0.009397	21.68	0.082012, 0.130321
0.515000	6	0.102000	0.028844	0.011776	28.28	0.071730, 0.132270
1.020000	6	0.073167	0.037435	0.015283	51.16	0.033881, 0.112452
2.020000	6	0.042333	0.026303	0.010738	62.13	0.014730, 0.069937

Level	Median	Min	Max	%of Ctrl(means)	%Reduction(means)
-1.000000	0.136500	0.088000	0.162000	.	.
0.125000	0.141000	0.094000	0.178000	104.3	-4.26
0.260000	0.109000	0.071000	0.139000	79.82	20.18
0.515000	0.095000	0.077000	0.147000	76.69	23.31
1.020000	0.067500	0.020000	0.128000	55.01	44.99
2.020000	0.029000	0.022000	0.087000	31.83	68.17

Analysis results for Variable: **WEIGHT Onion**

\*\*\*\*\*

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
5	30	8.91	<.0001

Dunnett -testing if each trt mean is significantly less than control

Williams-tests neg. trend. Check plots! TEST ASSUMES A MONOTONICALLY DECREASING DOSE RESPONSE.

Level	Mean	%Reduc Ctrl (means)	Dunnett p-value	Level	Isotonic mean	Williams p-value
Ctrl	0.133000	.	.	Ctrl	.	.
0.125000	0.138667	-4.26	0.912	0.125000	0.135833	0.565
0.260000	0.106167	20.18	0.205	0.260000	0.106167	0.077
0.515000	0.102000	23.31	0.139	0.515000	0.102000	0.051
1.020000	0.073167	44.99	0.004	1.020000	0.073167	<.001
2.020000	0.042333	68.17	<.001	2.020000	0.042333	<.001

RESULTS SUMMARY

	NOAEC	LOAEC
Dunnetts Test	0.515	1.02
Williams Test	0.515	1.02

MSD=The minimum diff Dunnett's was able detect as being statistically significant at .05

MSD: 0.04 %Change from ctrl the MSD represents: 30.37

# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

EPA MRID Number 47815102

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PARAMETER ESTIMATES FROM NONLINEAR MODELING

NOTE: Convergence criterion met.

WARNING: Do NOT report values below if convergence failed or convergence problems were noted.

Note that convergence does not necessarily mean a good model fit and/or good estimates!

LOOK AT GRAPHS! DO ESTIMATES MAKE SENSE? ICx estimates that fall outside the range of concentrations tested (along with their slope and CIs) are not likely to be reliable.

	Estimate	LowerCL	UpperCL
IC50	1.1157773	0.6900799	1.8040794
IC25	0.4715506	0.1995332	1.1144008
IC10	0.2171983	0.0600513	0.7855794
IC05	0.1365795	0.0289611	0.6441046

\*\*\*\*\*

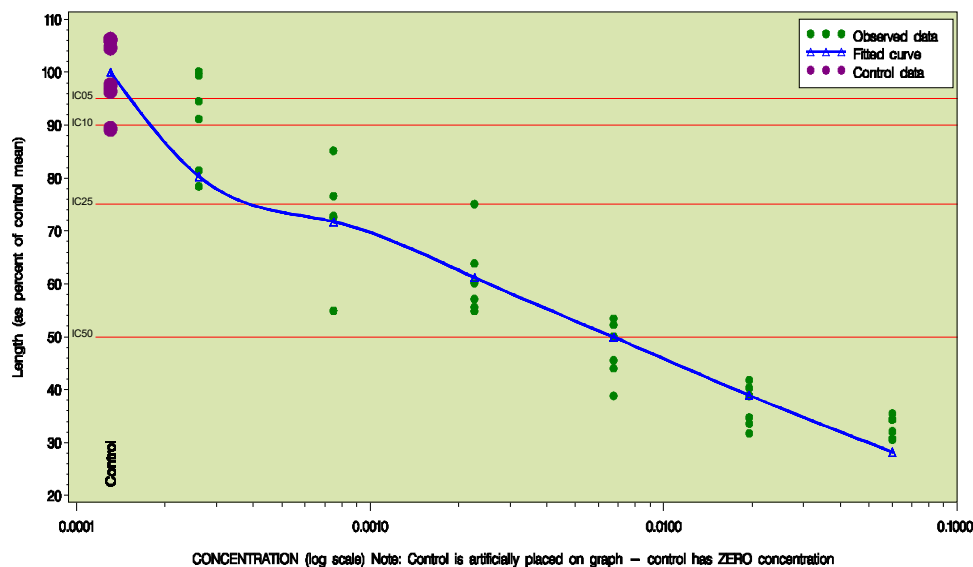
Slope	(LowerCL	UpperCL)
1.8032	1.1277	4.4966

OBSERVED vs PREDICTED TREATMENT GROUP MEANS

Level	N	Observed Mean	Predicted Mean	(Obs-Pred)	Pred % of Ctrl	Pred % Reduc from Ctrl
-1.000000	6	0.13	0.14	-0.00	101.58	-1.58
0.125000	6	0.14	0.13	0.01	97.19	2.81
0.260000	6	0.11	0.12	-0.01	88.68	11.32
0.515000	6	0.10	0.10	0.00	73.91	26.09
1.020000	6	0.07	0.07	0.00	53.64	46.36
2.020000	6	0.04	0.04	-0.00	32.61	67.39

## Length Inhibition Concentrations (ICx) for Soybean

VEGETATIVE VIGOR (Dicamba) 029801 47815102 (SAS v8.2, Sprouts v1.0) 12JAN2010



Analysis results for Variable: **LENGTH Soybean**

(SAS v9.2, Sprouts v1.0) VEGETATIVE VIGOR (Dicamba) 029801 47815102 12JAN2010

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Comparing Control vs. Inactive Ingredient



# Data Evaluation Report on the Acute Toxicity of Clarity 4.0 SL (AI: Dicamba) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

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Class	N	Mean	LowerCL	UpperCL	StdDev	StdErr	Minimum	Maximum
Control	6	53.5333	49.7259	57.3407	3.6280	1.4811	47.8000	56.8000
Inactive	6	51.1000	47.1249	55.0751	3.7879	1.5464	44.0000	54.4000
Diff (1-2)	—	2.4333	-2.3378	7.2044	3.7088	2.1413	—	—

\*\*\*\*\*

## TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals --- alpha-level=.01

Levenes test for homogeneity of variance (absolute residuals) -- alpha-level=.05

Use parametric analysis if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion

Test Stat	P-value	Test Stat	P-value	
0.986	0.880	1.412	0.239	USE PARAMETRIC TESTS

\*\*\*\*\*

## BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	CV(%)	95% Confidence Interval	
-1.000000	6	53.533333	3.628039	1.481141	6.78	49.725940,	57.340727
0.000261	6	48.633333	4.873466	1.989584	10.02	43.518945,	53.747722
0.000751	5	38.760000	5.904913	2.640757	15.23	31.428082,	46.091918
0.002270	6	32.733333	4.060870	1.657843	12.41	28.471711,	36.994955
0.006760	6	25.366667	2.978366	1.215913	11.74	22.241063,	28.492271
0.019600	6	19.733333	2.167641	0.884936	10.98	17.458534,	22.008133
0.060200	6	17.633333	1.120119	0.457287	6.35	16.457840,	18.808826

Level	Median	Min	Max	%of Ctrl (means)	%Reduction (means)
-1.000000	54.100000	47.800000	56.800000	.	.
0.000261	49.700000	42.000000	53.600000	90.85	9.15
0.000751	39.000000	29.400000	45.600000	72.40	27.60
0.002270	31.400000	29.400000	40.200000	61.15	38.85
0.006760	25.600000	20.800000	28.600000	47.38	52.62
0.019600	19.700000	17.000000	22.400000	36.86	63.14
0.060200	17.800000	16.400000	19.000000	32.94	67.06

Analysis results for Variable:LENGTH Soybean

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## PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
6	34	82.15	<.0001

Dunnett -testing if each trt mean is significantly less than control

Williams-tests neg. trend. Check plots! TEST ASSUMES A MONOTONICALLY DECREASING DOSE RESPONSE.

Level	Mean	%Reduc Ctrl (means)	Dunnett p-value	Level	Isotonic mean	Williams p-value
Ctrl	53.533333	.	.	Ctrl	.	.
0.000261	48.633333	9.15	0.066	0.000261	48.633333	0.015
0.000751	38.760000	27.60	<.001	0.000751	38.760000	<.001
0.002270	32.733333	38.85	<.001	0.002270	32.733333	<.001
0.006760	25.366667	52.62	<.001	0.006760	25.366667	<.001
0.019600	19.733333	63.14	<.001	0.019600	19.733333	<.001
0.060200	17.633333	67.06	<.001	0.060200	17.633333	<.001

## RESULTS SUMMARY

	NOAEC	LOAEC
Dunnetts Test	0.000261	0.000751
Williams Test	<lowest dose	0.000261

The minimum significant difference was not calculated due to unequal sample sizes.

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## PARAMETER ESTIMATES FROM NONLINEAR MODELING

NOTE: Convergence criterion met.

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concentrations tested (along with their slope and CIs) are not likely to be reliable.

	Estimate	LowerCL	UpperCL
IC50	0.0066922	0.0041140	0.0108861
IC25	0.0005132	0.0002247	0.0011722
IC10	0.0000509	0.0000153	0.0001687
IC05	0.0000128	0.0000030	0.0000534

\*\*\*\*\*

Slope (LowerCL , UpperCL)  
0.6048 0.5138 0.7350

## OBSERVED vs PREDICTED TREATMENT GROUP MEANS

Level	N	Observed Mean	Predicted Mean	(Obs-Pred)	Pred % of Ctrl	Pred % Reduc from Ctrl
-1.000000	6	53.53	54.98	-1.45	102.70	-2.70
0.000261	6	48.63	44.14	4.49	82.46	17.54
0.000751	5	38.76	39.43	-0.67	73.66	26.34
0.002270	6	32.73	33.64	-0.90	62.83	37.17
0.006760	6	25.37	27.43	-2.07	51.24	48.76
0.019600	6	19.73	21.38	-1.65	39.94	60.06
0.060200	6	17.63	15.50	2.13	28.96	71.04